PART 4

EXHIBITS TO DECLARATION OF SARAH BLAINE

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Frederick L. Licciardi, M.D.
Associate Director
Division of Reproductive Endocrinology
Program for IVF, Reproductive Surgery and Infertility

660 First Avenue, 5th Floor, New York, NY 10016
Telephone: (212) 263-7754
Facsimile: (212) 263-7853

April 29, 2004

Rabbi Jacobowitz, MD
52 Harrison Avenue
Brooklyn, NY 11211

Re: Chaya Grossbaum

Dear Rabbi Jacobowitz:

Thank you for referring Chaya and Mendell Grossbaum. As you know, she is a 23 year old female, G0P0, who is a carrier of cystic fibrosis mutation G542X. Her husband is positive for mutation 508. Her past history is unremarkable. Her physical exam is within normal limits.

We will be starting them in an IVF cycle as soon as possible. They have already contacted Mark Hughes to set up the biopsy testing.

I am here to serve as a resource in the treatment of infertility. Please feel free to contact me at 212-263-7754 if I can answer any of your questions or provide further clarification.

Again, thank you for this referral and for your confidence in the program.

Sincerely,

Dr Licciardi

Frederick L Licciardi, MD
FL: ar

George Stassa, M.D. (Ret.)
Richard Katz, M.D.
Morton Schneider, M.D.
Steven Albert, M.D.
Alison Bender Haimes, M.D.
Stephen D. Greenberg, M.D.

EAST RIVER MEDICAL IMAGING, PC

Barbara H. Braffman, M.D.
Douglas R. DeCorato, M.D.
Glenn Gray, M.D.
Gavin L. Duke, M.D.

519 & 523 East 72nd Street • New York, NY 10021 • 212-288-1575 • Fax: 212-288-7616 • www.eastriverimaging.com

FREDERICK LICCIARDI, MD
660 FIRST AVENUE 5TH FLOOR
NEW YORK, NY 10016

Patient Name: CHAYA GROSSBAUM
Exam Date: 4/23/2004

ID#:
Accession#: 4052024

Dear Dr. Licciardi,

HYSTEROSALPINGOGRAM

CLINICAL HISTORY: 23 year old female for infertility work-up.

Prior to a hysterosalpingogram, a scalp film of the pelvis was performed.

Phleboliths are noted within the pelvis.

After the patient was prepped in the usual fashion, a balloon tip catheter was inserted via the cervical os. Nonionic contrast was instilled via the catheter.

The uterus is normal in configuration. There are no filling defects.

Both fallopian tubes fill and there is free intraperitoneal spillage of contrast material bilaterally.

On delayed images, no peritubal adhesions are identified.

CONCLUSION

Normal hysterogram.

Very truly yours,

DOUGLAS DE CORATO, MD

FILMS
Transcribed by: CLAIR MC LOUGHLIN

Electronically signed by DOUGLAS DE CORATO, MD

EAST RIVER MEDICAL IMAGING, PC

☐ 515 East 72nd St., New York, NY 10021 (PET/CT)
☐ 519 East 72nd St., Suite 103, New York, NY 10021
☐ 523 East 72nd St., Level B & C, New York, NY 10021
(212) 288-1575 • FAX (212) 288-7616
www.eastriverimaging.com

Patient Name Chaya Grossbaum Appointment Date: _____ Time: _____ AM/PM

Clinical Information _____ Examination Requested HSG

X-RAYS
- ☐ Chest PA-Lat
- ☐ Sinuses
- ☐ Spine
  - Cervical
  - ☐ Thoracic
  - ☐ Lumbar
- ☐ Ribs ☐ Left ☐ Right
- ☐ Abdomen
  - ☐ Flat ☐ Erect
- ☐ IVP*
- ☐ Pelvis
- ☐ Extremity _____
- ☐ Other _____

FLUOROSCOPY
- ☐ UGI Series*
- ☐ Small Bowel*
- ☐ Gallbladder*
- ☐ Barium Enema*
- ☐ Esophagram*
- ☐ Video Esophagram*
- ☑ Hysterogram
- ☐ Other _____

NUCLEAR MEDICINE
- ☐ **PET/CT***
- ☐ Whole Body Bone Scan
- ☐ 3 Phase Bone Scan
- ☐ Limited Bone Scan
- ☐ Liver / Spleen Scan
- ☐ Gallium Scan
- ☐ Biliary Scan
- ☐ Renal Scan
- ☐ SPECT
- ☐ Other _____

SONOGRAPHY
- ☐ Abdominal*
- ☐ Gallbladder*
- ☐ Aorta*
- ☐ Obstetrical*
- ☐ Transvaginal
- ☐ Pelvic*
- ☐ Scrotal
- ☐ Thyroid
- ☐ Renal*
- ☐ Carotid Doppler
- ☐ Color Flow Doppler
- ☐ Hysterosonogram
- ☐ Other _____

CAT SCAN
- ☐ **W & W/Out Nonionic Contrast**
- ☐ Brain
- ☐ Sinuses
- ☐ Temporal Bones
- ☐ Orbits
- ☐ Facial Bone
- ☐ Nasopharynx
- ☐ Salivary Glands
- ☐ Neck Soft Tissues
- ☐ Larynx
- ☐ Cervical Spine
- ☐ Thoracic Spine
- ☐ Lumbar Spine
- ☐ Chest
- ☐ Abdomen*
- ☐ Pelvis*
- ☐ Extremity _____
- ☐ CT Angiogram _____
- ☐ CT Urinary Tract Stone
- ☐ CT Coronary Artery Calcification Scoring
- ☐ CT *Screening* Chest
- ☐ CT *Screening* Chest Abdomen, Pelvis*
- ☐ CT Virtual Colonoscopy*
- ☐ Other _____

MRI*
- ☐ **OPEN AIR MRI**
- ☐ G.E. 1.5T
- ☐ **W & W/Out Gadolinium Contrast**
- ☐ Brain
- ☐ MR Angiogram Brain
- ☐ MR Angiogram Neck
- ☐ MR Angiogram
- ☐ IAC/CP Angle
- ☐ Pituitary
- ☐ Cervical Spine
- ☐ Thoracic Spine
- ☐ Lumbar Spine
- ☐ Neck Soft Tissues
- ☐ TMJ
- ☐ Chest
- ☐ Abdomen
- ☐ Pelvis
- ☐ MR Arthrogram
- _____ Joint

MRI (cont)*
- ☐ Breast
- ☐ Prostate
- ☐ Shoulder ☐ Left ☐ Right
- ☐ Elbow ☐ Left ☐ Right
- ☐ Wrist ☐ Left ☐ Right
- ☐ Hand ☐ Left ☐ Right
- ☐ Hip ☐ Left ☐ Right
- ☐ Knee ☐ Left ☐ Right
- ☐ Ankle ☐ Left ☐ Right
- ☐ Foot ☐ Left ☐ Right
- ☐ MR Venogram _____
- ☐ Other _____

BONE DENSITOMETRY
- ☐ DEXA ☐ QCT

Fred L. Licciardi, MD
660 First Avenue, 4th Flr
New York, New York 10016

Requested By Dr. _____

Address _____

Phone 212-263-7754 Fax 212-263-7853

WE ONLY USE NONIONIC CONTRAST, IF PATIENT HAS AN ALLERGIC HISTORY, SEE REVERSE SIDE

*PLEASE SEE SPECIAL INSTRUCTIONS ON REVERSE SIDE

MRI & CT PATIENTS, SEE REVERSE SIDE

PLEASE NOTIFY OUR OFFICE AT LEAST 24 HOURS PRIOR TO CANCELLATION

Informed Consent to Perform an HIV Test

New York State Department of Health
AIDS Institute

The decision to have an HIV test is voluntary. In order to have an HIV test in New York State, you must give your consent in writing on the bottom of this form.

Testing for HIV Infection

Testing Methods:

There are a number of tests that can be done to show if you are infected with HIV, the virus that causes AIDS. Your provider or counselor can provide specific information on these tests. These tests involve collecting and testing blood, urine or oral fluid. The most common test for HIV is the HIV antibody test.

Meaning of HIV Test Results:

- A negative result on the HIV antibody test most likely means that you are not infected with HIV, but it may not show recent infection. If you think you have been exposed to HIV, you should take the test again three months after the last possible exposure.
- A positive result on the test means that you are infected with HIV and can infect others.
- Sometimes the HIV antibody test result is not clearly positive or negative, or may be a preliminary result. Your provider or counselor will explain this result, and may ask that you give your consent for further testing.

Confidential or Anonymous HIV Testing:

When you decide to have an HIV antibody test, you may choose either a confidential or an anonymous test.

- If you want your test result to become part of your medical record so it can be used for your medical care, you can have a confidential test done. A confidential test requires that you provide your name.
- If you do not want anyone to know your test results or that you were tested, you can have an anonymous test at an anonymous test site. You will not be asked your name, address or any other identifying information.
- If you receive an HIV positive test result at an anonymous test site approved by the NYS Department of Health, you will have the option of changing your test result to confidential by attaching your name to the test result. This will allow your test result to become part of your medical record.

Benefits to Testing:

There are many benefits to having an HIV test and knowing if you are infected.

If you receive an HIV negative test result:

- Your provider or counselor will tell you how to protect yourself from getting infected with HIV in the future.

If you receive an HIV positive test result:

- Your provider can give you medical care and treatment that can help you stay healthy and can manage your HIV illness.
- Your provider or counselor can tell you how to prevent passing the virus to your sexual or needle sharing partners.
- You can increase your chances of staying healthy by eating a well-balanced, nutritious diet, getting enough sleep, exercising, avoiding alcohol, tobacco, and recreational drugs, reducing stress and having regular check-ups.

If you are a woman who receives an HIV positive test result:

- If you are thinking about having a child, your provider will give you information to help you make informed choices about your health care and pregnancy.
- If you are pregnant, your doctor can provide the care you need and information about services and options available to you. Your provider can tell you about the risks of passing HIV infection to your baby, about medications given during pregnancy that can significantly reduce the risk of passing HIV to your baby, and the medical care available for babies who may be infected with HIV.
- If you have given birth to or breast fed a child since you were infected, your child will need to be tested for HIV and, if infected, may need additional care and treatment. Your provider can give you information about medical care available for children who may be infected with HIV.

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NEW YORK UNIVERSITY
SCHOOL OF MEDICINE

Program for IVF, Reproductive Surgery & Infertility
660 First Avenue- 5th floor
New York, NY 10016
212.263.8990 Fax 212.263.8827

Birth Information- The following information enables the NYU Program to furnish the CDC/SART with required information on pregnancy outcomes.

Mother's Name Chaya Grossbaum

Father's Name Menachem

Baby's Name(s) @

Date of Birth 5/25/05 Sex G C-section or Vaginal Delivery

Weight at Birth 6.13oz Length at Birth ?

(for multiple births please list above information for each baby on back of this form)

Delivered at St Clare's
(Name and Location of Hospital)

Obstetrician Name

Obstetrician Address

Did the mother experience any medical complications during or after pregnancy?
_____ Gestational diabetes _____ Pre-eclampsia _____ Surgery
Other NO

Did the baby(s) experience any medical complications?
NO

Did you have a reduction? _____ If yes, please specify the following:
Date of reduction_____
Original number of sacs_____ Number Reduced to_____

Physician who performed reduction

Thank you for your time.

CG051

Grossbaum –

NYU PIVF Chart Review Checklist

JUN 17 2004

Patient's Name Margenstern, Chaya Cycle Date

SSN D.O.B. M.D. TL

	Up To Date	Date	Needs to Be Updated	Initials	Follow Up	RN Initials
Update Labs	✓		HIV	[illegible]		
Sounding	✓			[illegible]		
Consents						
IVF	✓			[illegible]		
Research	✓	6/04		[illegible]		
Cryo	✓	4/04		[illegible]		
Emb Other Biopsy	✓	6/04		[illegible]		
Surgical Hx						
Medical Issues						
Allergies	NKA ✓					
Pap/Cultures	✓			[illegible]		
CBC*			✓	[illegible]		
G/P/A/E	G-0/P-0			[illegible]		
HSG			✓	[illegible]		
DX						
Protocol						
Semen Analysis	✓	4/04		[illegible]		
Donor Sperm	At NYU		Ordered	Pt informed no sperm no start		
Testicular Bx						
PGD						

*If medical history indicates anemia, bleeding, kidney or other illness, then obtain CBC immediately prior to retrieval, otherwise CBC can be performed in the 6 months prior to egg retrieval

(Both Pos. CF Carriers)

CG052

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

Restricted Laboratory Permit

June 22, 2004

Mark Hughes, MD
Genomic Center at Samaritan

Lab ID/PFI #:

5555 Conner Avenue Room A2064
Detroit, MI 48215

CLIA #: not provided

Dear Dr. Hughes,

This is in response to a request to submit a clinical specimen obtained in New York State, from the facility noted below, for testing at your laboratory. You are advised that the New York State Public Health Law and Department Regulations require that all specimens collected within the state be tested by laboratories that hold a New York State clinical laboratory permit. Permitted laboratories are required to hold departmental approval for any in-house developed tests, and all genetic and molecular oncology assays. Your laboratory does not currently hold a New York State clinical laboratory permit in the appropriate category, or does not hold New York State approval for the test requested, however based on the justification submitted, your laboratory has been issued a restricted permit for the following test only on the patient indicated below.

Test:	Preimplantation genetic diagnosis (PGD) for cystic fibrosis mutation delta F508 and G542X
Specimen Type:	single blastomere
Patient ID #:	
Patient Name:	Chaya Grossbaum
Referred by:	NYU Med Ctr PGM IVF Repro Surgery & Infertility-Andrology & Endo 660 First Ave 5th Floor Rm 640 New York, NY 10016
NYS PFI:	5289
Contact(s):	Lewis Krey, PhD, Phone: 212-263-6418

The patient, physician, and laboratory must acknowledge that these tests are being conducted outside the regulatory oversight of the Clinical Laboratory Evaluation Program and its quality assurance surveillance. Records of this exemption must be maintained and may be subject to audit and review. To apply for a New York State Clinical Laboratory permit, obtain guidelines for test approval submissions, or if you have any questions, please contact me in writing or by telephone at 518-402-2974. Application materials and additional information are also available on our website at www.wadsworth.org/labcert/clep/clep.html.

Sincerely,

Deirdre Astin

Deirdre Astin, M.S. MT (ASCP)
Assistant Director
Clinical Laboratory Evaluation Program

cc: Lewis Krey, PhD, NYU Med Ctr PGM IVF Repro Surgery & Infertility-Andrology & Endo, FAX: 212-263-7853
Michele Caggana, Sc.D.

DOH Accession 2835

CG053

TOTAL P.02

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

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Deirdre Astin

Deirdre Astin, M.S. MT (ASCP)
Assistant Director
Clinical Laboratory Evaluation Program

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Michele Caggana, Sc.D.

DOH Accession 2835

TOTAL P.02

CG054

Name Grossbaum-IVF Western Group DOB M.D. FL

Soc.Sec# Home phone Work phone

Partner's Name Grossbaum, Menachem Mendel Partner's D.O.B. / SS#

Address Brooklyn, NY 11213

IVF Checklist: Routine Tests for Patient & Partner

Date of Initial Consultation:		Results	Date	MD.
HSG/Hysteroscopy				
Sounding		7 1/2 cm	3/30/04	FL
Consent Forms and date signed				
		Results	**Date** 3/30/04	**RN**
Prolactin	(within 2 yrs)	7.3	3/30/04	KB
TSH	(within 2 yrs)	1.83	3/30/04	KB
Group and RH		O-Pos	3/30/04	KB
Varicella		Immune	3/30/04	KB
Rubella		Immune	3/30/04	KB
VDRL	(within 3 yrs)	Nonreactive	3/30/04	KB
Hepatitis Bs/Ag	(within 3 yrs)	Neg	3/30/04	KB
Hepatitis C	(within 3 yrs)	Neg	3/30/04	KB
HIV	(within 3 yrs)	Neg	4/19/04	
CBC	(within 6 months)		6/28/04	KB
FSH				
E2				
Chlamydia	(within 2 yrs)	Neg	3/30/04	KB
PAP Smear	(within 1 yr)	Neg	6/14/03	KB
Mammography	(if indicated)			
Partner		**Results:**	**Date:** 3/30/04	**RN**
HIV	(within 3 yrs)	Non Reactive		KB
Hepatitis Bs/Ag	(within 3 yrs)	Neg		KB
Hepatitis C	(within 3yrs)	Neg		KB
VDRL	(within 3 yrs)	Neg	3/30/04	KB
Cystic fibrosis	WIFE	Positive	4/19/04	KB
Semen Analysis	(within 1 yr)	Suitable for IVF	2/29/04	KB

Protocol Reg Lup/4 Imp as per Cycle Reservation: May 2004 Reviewed:

Protocol as per Cycle Reservation: Reviewed:

Protocol as per Cycle Reservation: Reviewed:

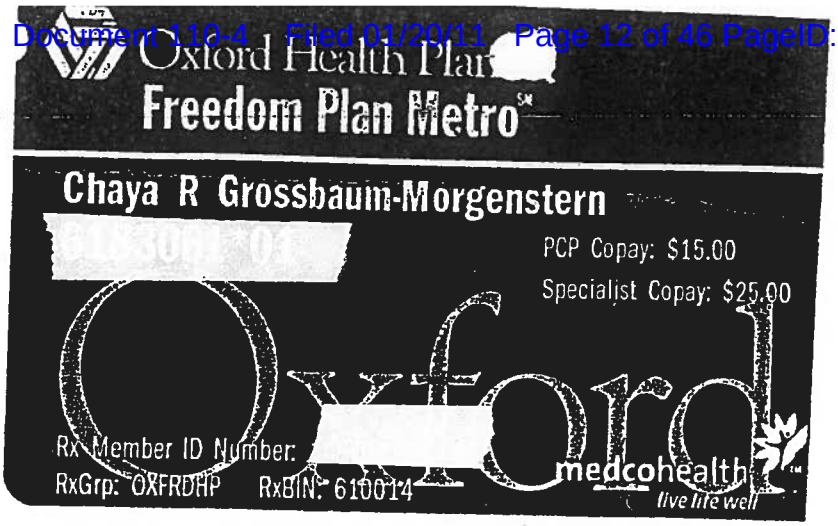
Orientation date: Wed, March 31, 2004 New Patient packet given: ✓

Diagnosis Notes: Embryo Biopsy per FL

( ) ICSI ( ) Epididymal ( ) Testicular Biopsy ( ) PGD ( ) Donor Oocyte waitlist ( )

Nurse signature of approval on day 2 or day three start

CG055


Oxford Health Plans
Freedom Plan Metro℠
Chaya R Grossbaum-Morgenstern
PCP Copay: $15.00
Specialist Copay: $25.00
Oxford
Rx Member ID Number:
RxGrp: OXFRDHP
RxBIN: 610014
medcohealth
live life well


Questions? Call Member Services:
800-444-6222
Speak with an Oxford On-Call Nu
800-201-4911
Precertification is required for hospital admissions, surgical procedures, a
certain diagnostic services. Check your Certificate of Coverage or Contr
for information on precertification and benefits. By the use of this card
hereby consent to the release to Oxford and its delegates of any medi
information needed to enable Oxford to administer my coverage.
Healthcare Providers Can Call: 800-666-1353
Submit Claims Electronically to Payer ID 06111
www.oxfordhealth.com
Pharmacy Customer Service: 800-905-0201
Pharmacists Call: 800-922-15
Oxford Health Insurance, Inc., PO Box 7082, Bridgeport, CT 06601

Date of Visit: _____

NYU SCHOOL OF MEDICI

ACCT. #: _____

Program for IVF, Reproductive Surgery & Infertility

☐ BERKELEY ☐ GRIFO ☑ LICCIARDI ☐ NOYES ☐ KUMP

PATIENT SUMMARY

Name: Chaya Rochel Grossbaum - Morgenstern Chaya Rochel (FIRST)

Home Address: _____

Brooklyn NY NY (STATE) 11213 (ZIP)

Home Phone: _____ Business Phone: _____

SS #: _____ DOB: _____ Age: 23 Marital Status: Married

Occupation: Administrative Asst. Employer: Keren Peulos

Bus. Address: 816 Eastern Pkwy

PARTNER SUMMARY

Name: Grossbaum Menachem Mendel, (FIRST)

SS #: _____ Age: 24 DOB: _____

Home Phone: _____ Business Phone: _____

Occupation: Locksmith Employer: Self

Payment is expected at the time services are rendered. Information is requested in the event billing to the insurer is required. Please present insurance card for verification.

PRIMARY INSURER: _____ PHONE: _____

Claims Address: _____

ID #: _____ GROUP #: _____

Name of Insured: _____ Relationship: _____

SECONDARY (If applicable, please complete):

Insurance Carrier: _____ PHONE: _____

Claims Address: _____

ID #: _____ GROUP #: _____

Name of Insured: _____ Relationship: _____

I authorize the release of any medical or other information necessary to process claims for services rendered by NYU PIVF and its physicians. I am responsiblefor the payment of all fees associated with services rendered by NYU PIVF and its physicians, including covered and non-covered services, deductible and co-payments. I agree to notify the office if changes of address, phone number of insurance coverage occurs.

_____ PATIENT SIGNATURE _____ DATE

Referring Physician: _____

Phone: _____

IVF INTAKE

CG058

NEW[illegible]RK UNIVERSITY MEDICAL C[illegible]ER

Program for IVF, Reproductive Surgery and Infertility
660 First Avenue, New York, NY 10016

Oocyte Retrieval Operative Report

Patient Name:

Patient ID#:

12.5 > 139/41.3 < 322

(6/25/04)

Date of Operation: 7/14/04

Pre-Op Dx: [illegible]

Post-Op Dx: [illegible]

Operation: *Ultrasound-guided follicular aspiration*

Surgeon: DR MCRAE

Assist. Surgeons: FELSTER

Anesthesia: IV TRV[illegible]

Est. Blood Loss: 15cc

Fluids: 1L

Technique:

Following the induction of intravenous sedation, the patient was placed in the dorsolithotomy position and preped and draped in the usual sterile fashion. Using the sterile vaginal intrasound probe, the pelvic organs were identified. Ultrasound guided follicular aspiration was performed using a negative pressure of 95 *mmHG. and* _____ *oocytes were retrieved from the right,* _____ *from the left. Hemostasis was confirmed. The instruments were removed and the patient was released to the recovery room in stable condition.*

Complications: NONE

33 oocytes.

Signature: _____ M.D.

Printed Name: NAYES M.D.

PS 714 A NYUMC Rev. 7/96

CG059

NYU Program for In Vitro Fertilization, Reproductive Surgery & Infertility

Pre-Operative Report

Name _____ D.O.B. _____

Date 7/11/04 S.S.N. _____

History:

35 Go.

for PGD CF

related infertility

Past History:

Surgical none

Medical none

Ob Gyn none

Family none

Medications Taken none

Allergies NKDA.

Physical Findings:

B/P 134/80 Pulse 90 Weight 194

Heart RRR

Lungs CTAB

Abd soft

Pelvic no NSDR bilaterally.

Clinical Impression: 35 Go PGD for CF mutation

Plan: weight obtained

Signature _____ M.D.

CG060

NYU Medical Center
CONSENT FOR ANESTHESIA

Patient: Sternbaum-Bergenstein, Clayton Age 24

I authorize Dr. Tzeborni and his associates and staff, and the NYU Medical Center and its staff to administer to me, the following anesthetic:
(me or name of patient)

TIVA (deep sedation) and use such as considered advisable and/or necessary.
(type of anesthesia-regional/general/MAC)

The risks, benefits and alternatives to this type of anesthesia have been explained to me. I understand that different types of anesthesia are often used in combination and I/the patient may receive such treatment. I also understand that conditions may arise in which alternate methods of anesthesia may be required and agree should such a condition arise.

I realize that my/the patient's breathing may be assisted by special equipment and that medications and fluids may be administered through an intravenous line. Additionally, monitoring devices or catheters may be inserted to help assess and treat my/the patient's status during anesthesia.

I have accurately informed the doctors about the last time I/the patient had something to eat or drink, any problems I/the patient have with my teeth, my/the patient's current medical status and medical history, medications or drugs which I/the patient am currently using or have taken in the past including natural supplements, and any allergies I/the patient may have.

I understand that certain risks and complications may result from the administration of anesthesia and pain relief medications which may include but not be limited to: dental damage, nausea and vomiting, hoarse voice, sore throat, discomfort at the site of an injection, headache, seizure, shortness of breath, bleeding, reactions to the medications, aspiration, infection, blood clots, numbness, loss of sensation, loss of limb function, paralysis, brain damage and death.

I understand the risks, benefits and alternatives to the type of anesthesia that has been chosen, I have read and fully understand the above consent, and all my questions have been answered to my satisfaction.

Signature _____ Date 7/14/04
(Patient or person authorized to sign)

Doctor's Statement: I have explained the risks, benefits and alternatives to the patient and have answered all of the patient's questions:

Physician's Signature _____ Date 7/14/04

GROSSBAUM- MORGENSTEIN
GHAYM

DATE 7/14/04

ATTENDING	Bertoni	EKG	☑
RESIDENT/CRNA	—	O_2SAT	☑
SURGEON	Noyes	$ETCO_2$	☑
DIAGNOSIS	☑ FEMALE INFERTILITY ☐ OTHER:	RR	☑
PROCEDURE	☑ T.V.U.G ASPIRATION ☐ OTHER:	PRECORDIAL	☑
ANES. TECHNIQUE	(TIVA)	HCT	40.2
HT 5'5"	WT 194 lbs T° 97.6	PLTS	302

BP 130/80 COR 78 reg S1S2 ō m/r/g LUNGS 18 clear

TEETH intact AIRWAY MP II FROM MO 5½ pl - supine

MEDS Protocol

ALLERGIES (INCLUDING SOY, EGGS, LATEX) NKDA - Soy, Eggs OK

NPO PMN TOBACCO Ø ETOH Ø REC. DRUGS Ø

PT INTERVIEWED AND EVALUATED ☑
CHART AND LABORATORY RESULTS REVIEWED ☑
ANESTHETIC PLAN/RISKS DISCUSSED, AGREED AND ACCEPTED ☑
ALL QUESTIONS ANSWERED ☑
CONSENT SIGNED ☑
POST OP INSTRUCTIONS GIVEN ☑
ASA: I
SIGNATURE [signature]

SHX: Ø (R) arm fx, GW, no problems

MHX: Ø

PT. REEVALUATED IMMEDIATELY PRIOR TO INDUCTION AND READY FOR ANESTHESIA
INITIALS [initials]

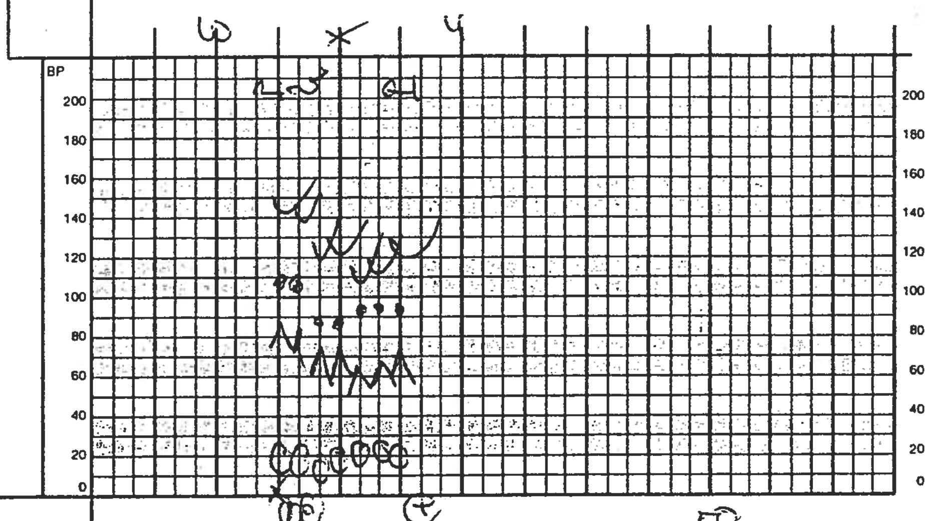
XRI . to on

MONITORS ON ☑
VITAL SIGNS CHECKED ☑
IV: 20 single Ⓛ ACF

① INDUCTION smooth
- spont. resp. maintained at all times

⊕ TRANSFER TO RR

RL	⊢———	700	CC
O_2 (NC)	5——		L/M
FENTANYL	100 100	120	MCG
LIDOCAINE	50 -25	75	MG
PROPOFOL	80 50 50 50 / ⊢——⊣	230 / 280	MG
REGLAN	15	15	MG
$ETCO_2$	✓ ✓ ✓		
RR	22 14 18		
O_2SAT	100 97 98		
EKG	NSR-NSR-NSR		



ANESTHESIA START 1014 END 1051
I WAS PRESENT FOR THE ENTIRE PROCEDURE.
SIGNATURE [signature]

RECOVERY ROOM NOTE: ARRIVAL TIME 1050
MENTAL STATUS
BP 130/80 HR 85 RR 18 O_2STAT 98 on RA

CG062

Patient I. GROSSBLUM, MORGENSTERN, CHAYA
SSN
Home Phone
Work Phone
Primary MD
MD @Transfer
Weight Blood Type O POS

Date of Retrieval 7/14/04 (cells)
Date of Transfer 7/15/04
Number of Embryos transferred 2
Number of Frozen Embryos
Trial Attempted with Wallace TomCat
Transfer Catheter type Wallace ✓ TomCat

7/16/04 WT = 197.2 lbs

Comments

Date	7/21/04	7/28/04	7/30/04	8/1/04	8/3/04	8/5/04	8/9/04
Cycle Day	21	28	30	32	34	36	40
E2		1222			1665		
P4	720	>20			7100		
BHCG		47	66	174	581	897	3942

OB Ultrasound Record

Date	Cycle Day	Gestational Sac(mm)	Yolk Sac (mm)	Fetal Pole (mm)	Fetal Heart	MD Sig
8/5/04	34	1 tiny 4mm 2 3 Lt OV - 3.1 x 4.8 Rt OV - 1.4 x 3.6	-	1 - 2 3	-	
8/9/04	40	1 ? 2 3	2.9	1 - 2 3	-	
scan text wed 8/18/04	49	1 16 2 3	315	1 6.7 2 3	D	

Obstetrician Name Phone
Address

CG063

Morganstern-Grossbaum results – 07/19/2004

Patient: Chaya Morganstern-Grossbaum – carrier - Exon 11, G542X Nt1756g>t
Partner: Menachem Grossbaum – carrier - Exon 10, dF508Nt1652 delCTT

Locus ID: 1080 Chromosome: 7q31.2 Gene: CFTR
OMIM: 602421

Biopsy done 7/17/2004 – began 10 am EDT, completed 11 am EDT
Quality is 1-4, where 1 is best
20 total tubes – 10 cells, 10 blanks

Sample	Quality	CF 10	CF 11	Call
2	2-8c	No deletion	T only	Possibly affected – ADO paternal
3	2-3c	No amp	No amp	No molecular signal
4	2-4c	No amp	G	Carrier at worst
7	2-7c	No amp	G	Carrier at worst
8	2-8c	No deletion	G/T	Carrier maternal – OK for transfer
9	2-4c	No amp	No amp	No molecular signal
10	2-4c	No deletion	G/T	Carrier maternal – OK for transfer
13	2-4c	No amp	G	Carrier at worst
14	2.-7c	No amp	No amp	No molecular signal
15	2-4c	No amp	G	Carrier at worst
CG		No deletion	G/T	Control – as expected
MG		Het. deletion	G	Control - as expected

Note: For sample 2, since only the mutant maternal allele was observed, it is possible that the paternal allele also dropped out of CF 10, and could be affected.

All controls and media blanks worked as expected. These data are very clear. All media blanks showed no evidence of exogenous DNA contamination.

Electronically signed,

Mark Hughes, M.D. Ph.D.

School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

IVF Summary

Patient Name: GROSSBAUM, CHAYA Med/Surg History: no SSN: DOB:

Partner Name: MENACHEM GROSSBAUM Phone(H): (W): Allergies: No Known Aller MD: Licciardi Age: 24

IVF Cycle#: 9188 ☑ ICSI ☐ Blast ☐ AH ☑ EB ☐ GLC Incubator Number 9 Review: Date:

Consent			
IVF-AH	☑ 4/19/2004	Donor Sperm	☐
IVF-ICSI	☑ 4/19/2004	Donor Egg	☐
CRYO	☑ 4/19/2004	Research IRB	☑
Comment	PGD ok 6/4/04. NY State PGD ok 6/4/04. Decline Research.		

Procedure	Initials		Date/Time
Retrieval	cfe	cmc	7/14/2004 10:35:00 AM
Sperm Preparation	aw	em	7/14/2004 10:25:00 AM
Insemination/ICSI	jl	em	7/14/2004 4:58:00 PM
Fertilization	cmc		7/15/2004 8:20:00 AM
Day 2 Check	em		7/16/2004 11:33:00 AM
Day 3 Check	pal		7/17/2004 9:04:00 AM
Assisted Hatching	jag	aa	7/17/2004 9:58:00 AM
Day 5 Check:	aa		7/19/2004 9:58:00 AM
Day 6 Check:	aa		7/20/2004 10:26:00 AM
Embryo Transfer	aa	jl	7/19/2004 3:27:00 PM
Cryopreservation Day			
Cryopreservation Day			
Cryopreservation Day			

Culture Data	Media:	Lot:
d0:	HTF+ plasm 6%	9012540657
d1:	Quinns Cleav	4154a
d3:	Quinns Blast	4154c

Oocyte Recipient ☐
Sperm Donor ☐

SPERM DATA		Sample	PP	Sperm Comments
Type	Fresh			
☐ Frozen ☐ Donor				
Preparation:	Isolate			
Supplement:	Chymotrypsin			
# Sperm/Drop:				
	Accession#:	40738		
	Vol (cc)	5.5	3	
	Conc (10 6	38	23	
	Motile (%)	42	92	
	Normal (%)			
	Progression	2	3.5	

Prev Attempts: Here = 0; Elsewhere = 0

Diagnosis: Primary = PGD; Secondary = Not Entered

EMBRYO TRANSFER

Embryologist: aa Tenaculum ☐
MD: fl Pain ☐
Catheter: Wallace
Difficulty: Easy
Blood:
Embryos Retained ☐
Comments:

EMBRYOLOGY SUMMARY

# Eggs Retrieved:	33
# Eggs Inseminated:	0
# Eggs ICSI:	15
# Eggs Fertilized (1pn):	0
# Eggs Fertilized (2pn):	10
# Eggs Fertilized (3pn):	0
# Embryos Assisted Hatching:	10
# Embryos Transferred:	2
# Embryos Frozen Day	0
# Embryos Frozen Day	0
# Embryos Frozen Day	0
# Eggs Late Fert:	
Embryo Quality:	good
# of Day 1 ICSI eggs:	0

Egg/Embryo Comments: PGD for CF.15/33 mature-10 fert w/ICSI
2 et, both blasts, both carriers

New York University
School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

Embryo Tracking

Patient Name: GROSSBAUM, CHAYA **Med/Surg History:** no **SSN:** **DOB:**

Partner Name: MENACHEM GROSSBAUM **Phone(H):** **(W):** **Allergies:** No Known Aller **MD:** Licciardi **Age:** 24

Cycle Number: 9188

Oocyte #	Day 0 Time: 7/2004 10:35:00 AM Grade	Maturity	Insem	Disp	Day 1 Time: 7/15/2004 8:20:00 AM #PN	Maturity	Embryo Description	Insem	Disp.	Day 2 Time: 7/16/2004 11:33:00 AM # Cells	% Frag	Grade	Embryo Description	MNB	Disp.	Day 3 Time: 7/17/2004 9:04:00 AM # Cells	% Frag	Grade	Embryo Description	AH	MNB	Disp
1	3	MII	I	C	0				C	2		1	0pn		C	4	5	2	0pn			D
2	3	MII	I	C	2				C	4	10	2			C	8	10	2		☑		C
3	3	MII	I	C	2				C	2		1.5			C	3	5	2	4-c	☑		C
4	3	MII	I	C	2		faint		C	2	5	1.5			C	4		2		☑		C
5	3	MII	I	C	0		deg		D													
6	3	MII	I	C	0		deg		D													
7	3	MII	I	C	2				C	5	10	2			C	7	5	2		☑		C
8	3	MII	I	C	2				C	4	15	3	asym		C	8	10	2		☑		C
9	3	MII	I	C	2				C	2	5	1.5			C	4	10	2		☑		C
10	3	MII	I	C	2				C	4		1.5			C	4		2	no growth	☑		C
11	3	MII	I	C	0				C	2		1.5	0pn		C	4	10	2	0PN			
12	3	MII	I	C	0				C	1					C	1						
13	3	MII	I	C	2				C	2		1.5			C	4		2		☑		C
14	3	MII	I	C	2				C	4	15	2.5			C	7	15	2.5		☑		C
15	3	MII	I	C	2				C	2	5	1.5			C	4	10	2		☑		C
16	3	MI		R																		

Grades:

1 - Symmetric blastomeres, no fragmentations or granularity
2 - Slight asymmetry, fragmentations or granularity
3 - Moderate asymmetry, fragmentations or granularity
4 - Severe asymmetry, fragmentations or granularity

Tuesday, July 20, 2004

CG066

New York University
School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

Embryo Tracking for Blastocyst Culture

Patient Name: GROSSBAUM, CHAYA **Med/Surg History:** no **SSN:** **DOB:**

Partner Name: MENACHEM GROSSBAUM **Phone(H):** (W) **Allergies:** No Known Aller **MD:** Licciardi **Age:** 24

Cycle Number: 9188

Embryo Drop #	Day 4 Embryo Stage	Day 4 Embryo Description	Day 4 Disp	Day 5 First Time: 9:58:00 AM Embryo Stage	Day 5 First Grade	Day 5 First Embryo Description	Day 5 First Disp.	Day 5 Second Embryo Stage	Day 5 Second Grade	Day 5 Second Embryo Description	Day 5 Second Disp.	Day 6 Time: Embryo Stage	Day 6 Grade	Day 6 Embryo Description	Day 6 Disp
2				morula		nice cav forming	D								
3				cleavage		6c	D								
4				cleavage		3c		cleavage		carrier	C	cleavage			D
7				morula				blast	1	carrier	T				
8				blast	2Cc	st to hatch		blast	3Bb	carrier	T				
9				cleavage		st to compact	D								
10				early morula				early morula		carrier	C	cleavage			D
13				morula				morula		carrier	C	blast	1		D
14				early morula			D								
15				morula				morula		carrier	C	morula			D

Grades:

1 - Early blastocyst; the blastocoel being less than half the volume of the embryo
2 - Blastocyst; the blastocoel being greater than half the volume of the embryo
3 - Full blastocyst; the blastocoel completely fills the embryo
4 - Expanded blastocyst; the blastocoel volume is now larger than that of the early embryo and the zona is thinning
5 - Hatching blastocyst; the trophectoderm has started to heniate through the zona
6 - Hatching blastocyst; the blastocyst has completely escaped from the zona

A - Tightly packed, many cells
B - Loosely grouped, several cells
C - Very few cells
D - Indistinct
a - Many cells forming a cohesive epithelium
b - Few cells forming a loose epithelium
c - Very few cells
d - Very poor

Tuesday, July 20, 2004

CG067

Patient Name: GROSSBAUM, CHAYA Med/Surg History: no SSN: DOB:

Partner Name: MENACHEM GROSSBAUM Phone(H): (W): Allergies: No Known Aller MD: Licciardi Age: 24

Cycle Number: 9188

Oocyte #	Day 0 Time: /2004 10:35:00 AM				Day 1 Time: 7/15/2004 8:20:00 AM				Day 2 Time: 7/16/2004 11:33:00 AM					Day 3 Time: 7/17/2004 9:04:00 AM					
	Grade	Maturity	Insem	Disp	#PN	Maturity	Embryo Description	Insem	Disp.	# Cells	% Frag	Grade	Embryo Description	MNB Disp.	# Cells	% Frag	Grade	Embryo Description	AH	MNB	Disp
17	3	MI		R																	
18	3	MI		R																	
19	3	GV		R																	
20	3	GV		R																	
21	3	GV		R																	
22	3	GV		R																	
23	3	GV		R																	
24	3	GV		R																	
25	3	GV		R																	
26	3	GV		R																	
27	3	GV		R																	
28	3	GV		R																	
29	2	GV		R																	
30	2	GV		R																	
31	2	GV		R																	
32	2	FZP		D																	
33	2	FZP		D																	

Grades:

1 - Symmetric blastomeres, no fragmentations or granularity
2 - Slight asymmetry, fragmentations or granularity
3 - Moderate asymmetry, fragmentations or granularity
4 - Severe asymmetry, fragmentations or granularity

Tuesday, July 20, 2004

Patient's Name: GROSSBAUM, CHAYA Med/Surg History:
Partner's Name: MENACHEM GROSSBAUM Phone (H): (W): SSN: DOB Age: 23 Primary MD: Licciardi
Allergies: Aff. MD: Not Entered

Cycle: 1 Procedure: IVF Start Date: 3/31/2004
# of Previous Attempts: 0
Here: 0 Elsewhere: 0
Series: 0 ICSI: Not Entered

G: NE EL/AB: NE SP/AB: NE ECT NE
P: NE Primary: Not Entered Not Entered
Protocol: FSH: Follistim Amps: 3 Sounding: 0 ○ Easy ○ Diff
HMG: Amps:
LUP: Lupron Misc:
Default from Most Recent Plan Protocol: OK
☐ Blast ☐ EB ☐ TB ☐ Co-culture

Comments: Not Entered
Ad
CF PGD c̄ Dr. Hughes
consents OK (initials)
SA 4/04 25 × 10⁶/ml 62% motile 29% normal morph
☐ Satellite ☐ DER ☐ Hormone Replacement Embryos to Transfer: 0
CBC Date: 5/25/04 Requision #:
CBC Result: Cycle Length:

#1 Cell 973 216 8640

Date:	6/4/04	6/11/04	[illegible]/04	7/6	7/8	7/8	7/9/04	7/10/04	7/11/04	7/12	7/13/04				
Cycle Day:	20	11 [illegible]	[illegible]	11 [illegible] 3	4	5	6	7	8	9	10				
Call Status:	left msg										no call				
Nurse Called:	IW														
FSH AM:		N					112		Ai						
PM:							38								
HMG AM:				225	225	225	150	150	150	HCG					
PM:										10,000					
Clomid:															
Lupron:		0.2cc	.2	.1	.1	.1	.1	.1	0.1	10					
Estrogen:			86	67			708		1064	2667.0	1400				
FSH:											4414				
LH:															
P4:	0.8	13													
HCG:															
PRL:											112				
TSH:															
Revised by:															
Date:															
Endometrium:			5.5						9R	11.5					
Ultrasound R:			PLO	CO					13.5 16 ×× 15 15	17 18 16.5 16 ×					
L:			PLO	PLO					16 15 14 ××	18 16 15.5 15.5 ×					
Comments:				ok				Can't come in sat							

- IVF Consent OK 4/04
- KS1 OK
- NO DEMAND
- AH OK
- NO RESEARCH
- CRYO CONSENT OK 4/04
- PGD CONSENTS OK 6/04
- NYS PGD OK 6/04

Find | [Ur]ology | IVF Sum/FET | HCG | Save | Close

CG069

Req# 0000228
Acct# 00022484
grossbaum, chaya

#

tpc

School of Medicine

660 First Avenue, 5th Floor New York, NY 10016

IVF Summary

Patient Name: Grossbaum, Chaya Phone(H): (W): SSN: DOB: Age:

Partner Name: MENACHEM GROSSBAUM Part.DOB: MD: Licciardi Alternate Id:

IVF Cycle#: 9188 ☑ ICSI ☐ Blast ☐ AH ☑ EB ☐ GLC Incubator Number 9 Review: Date:

Consent

IVF-AH	☑ 04/19/2004	Donor Sperm	☐
IVF-ICSI	☑ 04/19/2004	Donor Egg	☐
CRYO	☑ 04/19/2004	Research IRB	☐
PGD	☐	Egg Freeze	☐

Comment: PGD ok 6/4/04. NY State PGD ok 6/4/04. Decline Research.

Culture Data

	Media:	Lot:
d0:	HTF+ plasm 6%	9012540657
d1:	Quinns Cleav	4154a
d3:	Quinns Blast	4154c

~~Oocyte Recipient~~ ☐

Sperm Donor ☐

Procedure	Initials		Date/Time
Retrieval	cle	cmc	07/14/2004 10:35:00 AM
Sperm Preparation	aw	em	07/14/2004 10:25:00 AM
Insemination/ICSI	jl	em	07/14/2004 4:58:00 PM
Fertilization	cmc		07/15/2004 8:20:00 AM
Day 2 Check	em		07/16/2004 11:33:00 AM
Day 3 Check	pal		07/17/2004 9:04:00 AM
Day 4 Check			
Assisted Hatching	jag	aa	07/17/2004 9:58:00 AM
Day 5 Check:	aa		07/19/2004 9:58:00 AM
Day 6 Check:	aa		07/20/2004 10:26:00 AM
Embryo Transfer	aa	jl	07/19/2004 3:27:00 PM
Cryopreservation Day			
Cryopreservation Day			
Cryopreservation Day			

SPERM DATA

Type: Fresh ☐ Frozen ☐ Donor

Preparation: Isolate

Supplement: Chymotrypsin

Sperm/Drop:

	Sample	PP
Accession#:	40738	
Vol (cc)	5.5	3
Conc (10 6	38	23
Motile (%)	42	92
Normal (%)		
Progression	2	3.5

Sperm Comments:

Prev Attempts: Here = 0; Elsewhere = 0

Diagnosis: Primary = PGD; Secondary = Not Entered

EMBRYO TRANSFER

Embryologist: aa Tenaculum ☐

MD: fl Pain ☐

Catheter: Wallace

Difficulty: Easy

Blood:

Embryos Retained ☐

Comments:

EMBRYOLOGY SUMMARY

# Eggs Retrieved:	33	
# Eggs Inseminated:		0
# Eggs ICSI:		15
# Eggs Fertilized (1pn):		0
# Eggs Fertilized (2pn):		10
# Eggs Fertilized (3pn):		0
# Embryos Assisted Hatching:		10
# Embryos Transferred:		2
# Embryos Frozen Day	0	0
# Embryos Frozen Day	1	0
# Embryos Frozen Day	2	0
# Eggs Late Fert:		
Embryo Quality:	good	
# of Day 1 ICSI eggs:		0

NOT EVALUATED FOR INFECTIOUS DISEASES

WARNING: Advise recipient of communicable disease risks

Egg/Embryo Comments:

PGD for CF.15/33 mature-10 fert w/ICSI
2 et, both blasts, both carriers

One Malcolm Avenue
Teterboro, New Jersey 07608-1078
800-631-1390 Client Service
201-393-5000

Clinical Laboratory Report

Quest Diagnostics

Patient Name: GROSSBAUM,CHAYA 1024
Date Collected: 06/25/2004
Date Received: 06/26/2004
Date of Report: 06/29/2004
Sex: F
Age: 24
Client Name / Address: NYUMC PVT. PATIENTS 10270350
660 FIRST AVE. 5TH FLOOR
NEW YORK, NY 10016-3295
I.D. Number:
Account Number: T22484 1
Ordering Physician: LICCIARDI,FREDERIC
149704228
Patient I.D./Soc. Sec Number
T224840000228
C.L.I.A. # 31D0696246
Specimen Number
Time Collected: 0936

TEST NAME	RESULT OUT OF RANGE	RESULT IN RANGE	UNITS	REFERENCE RANGE
CBC W/ DIFF & PLT				
WBC	12.5 H		Thous/mcL	3.8-10.8
RBC		4.85	Mill/mcL	3.80-5.10
HEMOGLOBIN		13.9	g/dL	11.7-15.5
HEMATOCRIT		41.3	%	35.0-45.0
MCV		85.0	fL	80.0-100.0
MCH		28.7	pg	27.0-33.0
MCHC		33.7	g/dL	32.0-36.0
RDW		13.5	%	11.0-15.0
PLATELET COUNT		322	Thous/mcL	140-400
MPV		8.8	fL	7.5-11.5
TOTAL NEUTROPHILS,%		68.3	%	38-80
TOTAL LYMPHOCYTES,%		23.8	%	15-49
MONOCYTES,%		5.8	%	0-13
EOSINOPHILS,%		1.6	%	0-8
BASOPHILS,%		0.5	%	0-2
NEUTROPHILS,ABSOLUTE	8538 H		Cells/mcL	1500-7800
LYMPHOCYTES,ABSOLUTE		2975	Cells/mcL	850-3900
MONOCYTES,ABSOLUTE		725	Cells/mcL	200-950
EOSINOPHILS,ABSOLUTE		200	Cells/mcL	15-550
BASOPHILS,ABSOLUTE		63	Cells/mcL	0-200
DIFFERENTIAL				

An instrument differential was performed.

>> END OF REPORT - GROSSBAUM,CHAYA 50972847 <<

Repeat

CG071

Donald D. Luff, M.D.
William E. Tarr, M.D.

NR = Test referred by: NP = Test performed by:
Quest Diagnostics, Nichols Institute,
33608 Ortega Hwy.
San Juan Capistrano, CA 92690

MP = Test Performed by
Quest Diagnostics, ,
1651 Third Avenue, N

NYU Program for In Vitro Fertilization,
Reproductive Surgery & Infertility
660 First Avenue
New York, New York 10016
212-263-8990

IVF-Post Embryo Transfer
Patient Instructions

If your transfer occurs 3 days after retrieval, you should continue Medrol® (methylprednisolone) and tetracycline as prescribed through the night of your embryo transfer.

If your transfer occurs 5 days after retrieval, your Medrol® (methylprednisolone) and tetracycline protocols should be completed already.

Continue your progesterone injections (1 cc intramuscular injected daily) until further notification. It is common to experience mild abdominal cramping during the course of progesterone therapy. While the package insert of progesterone warns of taking this medication during pregnancy, the compound is chemically the same to the progesterone that your body makes naturally, and has not been found to cause harm to your pregnancy.

You will need a progesterone blood test one week from the date of your egg retrieval. Please return to our office on 2/21/07. Satellite patients should contact their satellite office for an appointment for this test.

A pregnancy test will be performed two weeks after the date of your egg retrieval. Please return to our office on 2/28/07. Satellite patients should contact their satellite office for an appointment for this test

Avoid heavy lifting, intercourse, high impact exercise and tub baths (showers are permitted) until after the date of your pregnancy test. Nothing should be placed in the vagina until after the date of your pregnancy test. Abstain from alcohol.

You may resume normal activities tomorrow.

Phone your physician if the following occurs:
- Temperature greater than 100.5°F
- Vaginal bleeding
- Severe abdominal cramping

Patient Signature _____ Date _____

_____	Alan S. Berkeley, M.D.	212-263-7629
_____	Jamie A.Grifo, M.D., Ph.D.	212-263-7978
_____	Nicole Noyes, M.D.	212-263-7981
X	Frederick Licciardi, M.D.	212-263-7754
_____	Lisa Kump-Checchio, M.D.	212-263-0040

5/04

Printed Family Name: GROSSBAUM, CHAYA

genesis
genetics institute

HIPPA Participant Authorization

Our Commitment to the Privacy & Security of Your Health Information

We are dedicated to assisting you in your medical care, and we are also deeply committed to maintaining your privacy. During the course of your treatment(s) in this Preimplantation Genetic Diagnosis (PGD) protocol, it will be important for us to discuss and exchange certain personal information about you with other members of your health care team. This information is called your Protected Health Information (PHI). Because these individuals (for example, your geneticist, genetic counselor, IVF center, PGD doctors/scientists, transplantation team) are often at different institutions/states/countries, we need your permission beforehand in order to participate in these medical and scientific discussions about you. Nonetheless, each individual on your health care team does not need to know or have access to everything. We believe in a minimal "need-to-know" approach to the exchange of your health information.

Doctors have exchanged this sort of information for years in the practice of medicine. However, in this day of electronic databases, there is (rightfully) concern about how private health information about you is collected and shared. For that reason, we applaud the fact that the US Federal Government has now issued a regulation to provide safeguards for the privacy and security of health information that may identify you. This rule was issued under a law called the Health Insurance Portability and Accountability Act (HIPPA). This document that you are now reading, is called a "Participant Authorization," and it describes your rights and explains how your health information will be used and disclosed during your care.

Section A: Protocol Information

Protocol Title:	Molecular & Cytogenetic Testing of Human Pre-embryos for Genetic Disease
Principal Investigator:	Mark R. Hughes, MD, PhD
Address:	The Genesis Genetics Institute The Charles Trowbridge Historical House 1380 East Jefferson Avenue Detroit, MI 48207
Phone & Fax	313-544-4006

You have agreed to participate in this research study and you have signed a separated "Informed Consent" that explains the procedures, the risks and the benefits of this protocol. This Authorization Form gives more detailed information about how your health information will be protected. By signing this document you are permitting The Genesis Genetics Institute to use your Protected Health Information (PHI) for research purposes and in your health care. You are also allowing us to exchange PHI with other members of your medical team at outside organizations

Section B: Protected Health Information

1. **What PHI is collected and might be shared amongst your medical team?**
The following PHI items that have been checked below will be collected, used for research and may be disclosed or released during your involvement in this research project:

- ☒ Your names and potentially the names of your child(ren)
- ☒ Your Address, Telephone Numbers, E-mail Address.
- ☒ Dates (e.g. birth, menstrual cycle, IVF-related dates, delivery date)
- ☐ Biometric Identifiers (e.g. photograph, finger print, voice print)
- ☒ Identifying Number (e.g. clinic, protocol, insurance, social security, medical record)
- ☒ Genetic mutation, marker, polymorphism data, and your family genetic history

2. **Why is this information needed?**
This information is important to your health care providers and members of the research team in order to contact you during this protocol, as part of this research project, and in your treatment.

3. **Which project personnel may use or disclose your PHI?**
The following individuals and organizations may use or disclose your PHI for <u>THIS</u> protocol <u>ONLY</u>.

- The Principal Investigator, Dr. Hughes, and key personnel at Genesis Genetics who are involved in this protocol and in your care. This is limited to individuals who require access in the performance of their duties (for example: to provide treatment, to ensure integrity of the data, accounting or billing matters, etc).
- Collaborating health care professionals (e.g. your reproductive endocrinologist, embryologist, nurse coordinator, genetic counselor, molecular biologist/laboratory that found the gene mutaton in your family, transplantation physician, geneticist, etc).
- The Human Investigation Committee and the Institutional Review Boards of the Genesis Genetics Institute and the University, and at your clinic at a collaborating institution(s). (These Boards oversee research protocols and protect patient interests. They generally do not request any of your information unless there is a concern about the protocol or about your well being. Since your health care providers are at different universities/organizations, each one may have separate committees and boards, and (sorry), more forms like this one.)
- Your health insurance company, but only if we receive <u>separate, written, and prior authorization</u> from you to release any PHI to them.

4. **Can you change your mind?**
You may withdraw your permission for the use and disclosure of your PHI at any time, but you must do so in writing to the Principal Investigator at the address on the first page of this form. After receiving the request to withdraw from the protocol, you will be contacted concerning a plan for your withdrawl from the protocol. Even if you withdraw your permission, you also are withdrawn from the research protocol. The Principal Investigator may still use your PHI that was collected prior to your written request, if that information is necessary to the integrity of the study.

You will be given a copy of this Participant Authorization Form, describing your confidentiality and privacy rights for this study. By signing this document you are authorizing the collection and potential exchange of this information described above.

Chaya R. Grossbaum		7/14/04
Printed Woman's Name	Woman's Signature	Date
Menachem M Grossbaum		7/14/04
Printed Man's Name	Man's Signature	Date

NYU School of Medicine

Program For IVF Andrology Laboratory

660 First Avenue, 5th Fl.

New York, NY 10016

Routine Semen Analysis: _____

IVF Semen Analysis: ✓

Patient's Name: GROSSBAUM, MENACHEM M

Spouse's Name GROSSBAUM, CHAYA R.

Physician's Name Dr LICCIARDI Date: 4/29/2004

Time Specimen collected: 1015 AM Time Specimen received: 1115 AM (drop off) Time Specimen analyzed: 1200 PM	Semen Analysis 1	Semen Analysis 2	IUI/ Sperm Prep
Lab Accession ID#	20040609		
Volume (cc) Normal ≥ 2.0 cc)	5.8		
Appearence (greyish, white / opaque)	greyish / opaque	Liquefaction: Normal	
Viscosity (1-Normal, 2-Moderate, 3-High)	1		
pH ≥ 7.2	8.0		
Count (10^6 / cc) (≥ 20 x 10^6 / cc)	28 x 10^6/cc		
% Motility (≥50%)	62%		
Grade of Forward Progression (≥2+)	2+ to 3		
PMN count (<1.0 x 10^6/cc)	0.07 x 10^6/cc		
Agglutination (None)	None		
Fructose Test: Positive, Negative, or N/A	N/A		
Indicate if present: (extracellular debris, other)	Mod debris		
% Normal oval forms(normal is defined as ≥ 14% Normal Oval heads)	2 low		
% Large Head(s)	1		
% Small Head(s)	2		
% Irregular Head(s)	55		
% Tapered Head(s)	26		
% Blunted Tail(s)	2		
% Coiled Tail(s)	9		
% Cytoplasmic Droplet(s)	1		
% Duplicate Head(s)	0		
% Duplicate Tail(s)	2		

Interpretation: pt auth release of SAR to Chaya Rachel Grossbaum; sample collected off-site via intercourse using Mole Park condom

Abstinence: 2 days

SUITABLE FOR IVF (Note: LOW % Normal Oval Forms)

Lab Tech Init. MJ lab Supervisor Init. ZY Lab Director Init. THL 4/29/04

CG076

(Ref: W.H.O. Lab Manual for the Examination of Human Semen, Cambridge Press, 1999, 4th ed.

564 NYU/MC 12/03

EAST RIVER MEDICAL IMAGING, PC

☐ 515 East 72nd St., New York, NY 10021 (PET/CT)
☐ 519 East 72nd St., Suite 103, New York, NY 10021
☐ 523 East 72nd St., Level B & C, New York, NY 10021
(212) 288-1575 FAX (212) 288-7616
www.eastriverimaging.com

Richard Katz, M.D. • Morton Schneider, M.D.
Steven Albert, M.D. • Alison Bender Haimes, M.D.
Stephen D. Greenberg, M.D. • Barbara H. Braffman, M.D.
Douglas R. DeCorato, M.D. • Glenn G. Gray, M.D.
Gavin L. Duke, M.D. • George Stassa, M.D. (Ret)

Patient Name Chaya Grossbaum Appointment Date: _____ Time: _____ AM/PM

Clinical Information _____ Examination Requested HSG

X-RAYS
- ☐ Chest PA-Lat
- ☐ Sinuses
- ☐ Spine
  - ☐ Cervical
  - ☐ Thoracic
  - ☐ Lumbar
- ☐ Ribs ☐ Left ☐ Right
- ☐ Abdomen
  - ☐ Flat ☐ Erect
- ☐ IVP*
- ☐ Pelvis
- ☐ Extremity _____
- ☐ Other _____

FLUOROSCOPY
- ☐ UGI Series*
- ☐ Small Bowel*
- ☐ Gallbladder*
- ☐ Barium Enema*
- ☐ Esophagram*
- ☐ Video Esophagram*
- ☑ Hysterogram
- ☐ Other _____

NUCLEAR MEDICINE
- ☐ PET/CT*
- ☐ Whole Body Bone Scan
- ☐ 3 Phase Bone Scan
- ☐ Limited Bone Scan
- ☐ Liver / Spleen Scan
- ☐ Gallium Scan
- ☐ Biliary Scan
- ☐ Renal Scan
- ☐ SPECT
- ☐ Other _____

SONOGRAPHY
- ☐ Abdominal*
- ☐ Gallbladder*
- ☐ Aorta*
- ☐ Obstetrical*
- ☐ Transvaginal
- ☐ Pelvic*
- ☐ Scrotal
- ☐ Thyroid
- ☐ Renal*
- ☐ Carotid Doppler
- ☐ Color Flow Doppler
- ☐ Hysterosonogram
- ☐ Other _____

CAT SCAN
- ☐ **W & W/Out Nonionic Contrast**
- ☐ Brain
- ☐ Sinuses
- ☐ Temporal Bones
- ☐ Orbits
- ☐ Facial Bone
- ☐ Nasopharynx
- ☐ Salivary Glands
- ☐ Neck Soft Tissues
- ☐ Larynx
- ☐ Cervical Spine
- ☐ Thoracic Spine
- ☐ Lumbar Spine
- ☐ Chest
- ☐ Abdomen*
- ☐ Pelvis*
- ☐ Extremity _____
- ☐ CT Angiogram _____
- ☐ CT Urinary Tract Stone
- ☐ CT Coronary Artery Calcification Scoring
- ☐ CT *Screening* Chest
- ☐ CT *Screening* Chest Abdomen, Pelvis*
- ☐ CT Virtual Colonoscopy*
- ☐ Other _____

MRI*
- ☐ **OPEN AIR MRI**
- ☐ G.E. 1.5T
- ☐ **W & W/Out Gadolinium Contrast**
- ☐ Brain
- ☐ MR Angiogram Brain
- ☐ MR Angiogram Neck
- ☐ MR Angiogram
- ☐ IAC/CP Angle
- ☐ Pituitary
- ☐ Cervical Spine
- ☐ Thoracic Spine
- ☐ Lumbar Spine
- ☐ Neck Soft Tissues
- ☐ TMJ
- ☐ Chest
- ☐ Abdomen
- ☐ Pelvis
- ☐ MR Arthrogram
- _____ Joint

MRI (cont)*
- ☐ Breast
- ☐ Prostate
- ☐ Shoulder ☐ Left ☐ Right
- ☐ Elbow ☐ Left ☐ Right
- ☐ Wrist ☐ Left ☐ Right
- ☐ Hand ☐ Left ☐ Right
- ☐ Hip ☐ Left ☐ Right
- ☐ Knee ☐ Left ☐ Right
- ☐ Ankle ☐ Left ☐ Right
- ☐ Foot ☐ Left ☐ Right
- ☐ MR Venogram _____
- ☐ Other _____

BONE DENSITOMETRY
- ☐ DEXA ☐ QCT

Fred L. Licciardi, MD
660 First Avenue, 4th Floor
New York, New York 10016

Requested By Dr. _____
Address _____
Phone 212-263-7754 Fax 212-263-7853

WE ONLY USE NONIONIC CONTRAST, IF PATIENT HAS AN ALLERGIC HISTORY, SEE REVERSE SIDE

*PLEASE SEE SPECIAL INSTRUCTIONS ON REVERSE SIDE

MRI & CT PATIENTS, SEE REVERSE SIDE

PLEASE NOTIFY OUR OFFICE AT LEAST 24 HOURS PRIOR TO CANCELLATION

* Rachi (Rochel). *

Name Grossbaum, Chaya age 23 DOB Date 3-30-04

Partner Menachem Grossbaum age 24 DOB

Referred by (Mendel) *

History: 23 y/o G0P0 - 6 weeks ago. (on pill)

Both CF carriers

HSG:

Pregnancy History

date	gest age	outcome	complications

GYN History:

Menses: age____ interval 28 duration: 5-7 flow____

molimina____ dysmenorrhea Ø

galac____ hirsutism____ contraception: on OCP.

last PAP Summer 03.

last mammo Ø.

IUD use Ø PID Ø DES Ø

Medical History: Ø

Medications OCP.

Surgical History: Ø

Smoking Ø ETOH Ø Drugs Ø Allergies Ø

Family History:

	Female	Male
Mother	OK	OK
Father	heart Dx s/p MI. Sister - Dwarfism	OK
Siblings	OK	OK

Known genetic abnormalities CF carrier Blood clotting disorders Ø Family history of breast, uterine or ovarian cancer Ø

Partner data:
Medical Ø

Surgical Ø

allergies Ø medications Ø
smoking Ø ETOH Ø drugs Ø
Semen Analysis:

date	volume	concentration	motility	morphology	lab
	Nevers				

Physical Exam:
weight 196 height ____ BP 130/80

Habitus — Grey hair in front. Saw [illegible]
HEENT (wnl)
Skin (wnl)
Hirsutism (wnl)
Neck (wnl)
Thyroid (wnl)
Lungs (wnl)
Heart (wnl)
Breasts (R wnl) (L wnl)
Abdomen (wnl)
Ext Genitalia (wnl)
Vagina (wnl)
Cervix (wnl)
Uterus wnl (anti)/retro/mid
Adenexia (R wnl L wnl)
Rectal wnl
Ultrasound: [illegible]

Sounding: [illegible] 7.5 cm easy up

Impression 23 sy [illegible]

Plan [illegible]
(1) 5/2 [illegible]
(2) [illegible]

CG079

New York University School of Medicine
Program for IVF, Reproductive Surgery and Infertility
660 First Avenue, 5th Floor, New York, NY 10016

Date:

Patient: Grossbaum Chaya

LMP:

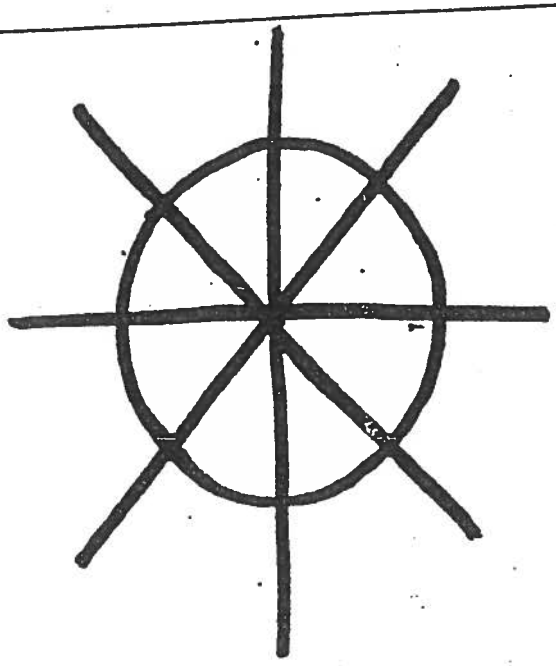


Diagram depicts patients in Lithotomy position

Depth: 7 1/2 CM

Position:

Comments:

Physicians Signature:

Sounding Sheet
11/25/02

CG080

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Program for IVF,
Reproductive Surgery
and Infertility

660 First Avenue, 5th Floor, New York, NY 10016
Telephone: (212) 263-8990
Facsimile: (212) 263-8827
www.nyuivf.com

IN VITRO FERTILIZATION / EMBRYO TRANSFER ("IVF - ET") PROGRAM CONSENT FORM OPTIONS FOR "INTRACELLULAR SPERM INJECTION" AND "ASSISTED HATCHING"

I, Chaya Rachel Grossbaum - Meiraczkerm, and my partner, Menachem Mendel Grossbaum, have been unable to become pregnant due to one of the following reasons: absent fallopian tubes, blocked fallopian tubes that are either uncorrectable by surgery or that surgery has failed to correct, endometriosis, male factor infertility, or some other condition not treatable by any other currently available method, or "unexplained infertility". I and my partner request, authorize, and consent to the performance of the procedure of in vitro fertilization and embryo transfer (IVF/ET, sometimes referred to as a "test-tube baby") with, if necessary, "intracytoplasmic sperm injection" of my oocytes and / or "assisted hatching" of my fertilized oocytes / embryos. These procedures are to be performed by the clinical and laboratory staffs at NYU School of Medicine - Program for In Vitro Fertilization, Reproductive Surgery and Infertility (PIVF) or at one of its affiliated programs.

A. The following is a general outline of the steps that may be required in these procedures. My partner and I consent to the performance of these steps unless indicated otherwise below.

1. "Fertility drugs" (gonadotropin releasing hormone agonist or antagonist, clomiphene, human menopausal gonadotropins [Pergonal^R, Humegon^R, Repronex^R, Fertinex^R and/or Metrodin^R], recombinant gonadotropins [Follistim^R and/or Gonal F^R] and/or human chorionic gonadotropin) will be administered to me to produce ovulation, or release of the egg(s), at a predictable time. Collection of the eggs will be scheduled to occur just before their predicted release. Progesterone treatments will also be initiated immediately after egg collection to help maintain the early stages of pregnancy

2. Antibiotics (tetracycline, 250 mg four times a day for four consecutive days beginning on the day of follicular aspiration) and corticosteroids (Medrol, 16 mg daily) will also be required during the IVF cycle.

3. Blood will be drawn for daily tests to determine my response to these medications and to assist in predicting the time of expected ovulation. About 1 to 3 teaspoons of blood will be taken each time.

4. Ultrasound examinations (sonograms) will be performed to monitor the growth of the follicles. Ultrasonography is a diagnostic procedure using sound waves that provides a "picture" of the ovaries and the growing follicle(s).

5. An ultrasonographic follicular aspiration will be performed 1 to 4 hours before I am expected to ovulate by insertion of a needle through the vaginal wall into my ovaries to obtain the egg(s) contained within the follicle. Sedation will be administered during aspiration by the anesthesiologist who will explain the risks of anesthesia.

6. My partner will provide a sperm specimen by self-masturbation or, if necessary, by surgical means. Alternatively, a Donor sperm specimen will be obtained in advance from a Sperm Bank licensed by the State of New York. The sperm specimen will be prepared for insemination by the embryology laboratory at PIVF. An additional consent form must be signed if the sperm specimen is obtained during a surgical procedure or from the NYUMC Sperm Bank or a commercial sperm bank.

7. The eggs obtained at retrieval will be appropriately exposed to sperm for fertilization depending on my and my partner's medical history. In most cases the egg(s) and sperm will be processed and placed together in a drop of culture medium in the laboratory to allow fertilization to occur. However, my partner and I understand that we also can accept or decline the option to have "intracytoplasmic sperm injection" (ICSI) performed to facilitate the fertilization process. This procedure is routinely recommended in severe male

factor cases (very low sperm count and/or motility), in cases in which sperm specimens are obtained by surgical procedures or in cases in which a poor fertilization rate was observed in a previous IVF cycle(s). During this procedure all oocytes will be exposed to an enzyme to remove the surrounding granulosa cells without apparent risk in order to assess oocyte maturity. Individual sperm immobilized in a sterile, highly viscous solution are then captured and injected into each mature egg using a microscope and specially designed tools. We understand that there will be a charge ($2500) for this micromanipulation procedure.

We accept CRG-M mmg **/ decline** _____ **the option for ICSI .**
(Please initial to indicate your decision)

8. The fertilized egg(s) will be transferred into culture dishes with culture medium necessary for growth.

9. Each individual embryo will be evaluated on Days 2-6 post-retrieval for general appearance, rate of cell division and development and thickness of the zona pellucida or outer coating of the egg/embryo.

10. At three (3) or five (5) days following oocyte retrieval, embryo(s) will be transferred into my uterus by means of a small tube inserted through my cervix. Embryos transferred on Day 3 will usually be in the cleavage stage (4-10+ cells) and those on Day 5 will usually be in morula or blastocyst stage. We understand that there is no charge for blastocyst culture. We understand that the day of transfer and the number of embryos recommended for transfer (either at cleavage, morula or blastocyst stage) will be determined by PIVF policy and will be depend on embryo development rate and quality as well as other factors, including but not limited to, patient age, prior IVF history and program statistics to be discussed with us by the PIVF physicians. Additional viable embryos of good quality on Days 2, 3, 5 and/or 6 will be frozen for cryostorage in liquid nitrogen at this time subject to our signing a separate consent form which also lists the charges for cryopreservation and cryostorage.

11. My partner and I understand that the PIVF embryology staff may recommend "assisted hatching" for our embryos prior to transfer to the uterus on Day 3. We understand that this procedure is routinely recommended whenever the female partner is 38 years of age or older or when younger patients have poor quality embryos as judged by their rate of division and microscopic appearance. In this micromanipulation procedure the normal hatching process is assisted by the "drilling" of a small opening in the zona pellucida by the local administration of minute amounts of sterile acidic Tyrode's solution, using a microscope with specially designed tools. We also understand that there is no charge for " assisted hatching" and that we can accept or decline the option to have this procedure performed on our embryos.

We accept CRG-M mmg **/ decline** _____ **the option for "Assisted Hatching."**
(Please initial to indicate your decision)

12. As part of the IVF protocol, blood samples will be drawn at regular intervals over the three (3) weeks after transfer of the embryo(s) to determine if pregnancy has occurred and is proceeding normally. About 1 to 3 teaspoons of blood will be taken each time. In addition an ultrasound examination will be performed approximately 32 days after transfer to visualize the fetal sac(s) present in the uterus and to examine for a fetal heart beat(s).

B. My partner and I understand that a cycle of IVF/ET may be discontinued at any stage if it is deemed medically advisable by the PIVF Director or his designee(s). In addition, we also understand that any of the following may occur which would prevent the establishment of a pregnancy:

1. The time of ovulation may be unpredictable, may have already occurred, or may not occur in the monitored cycle, thus preventing any attempt of obtaining an egg.

2. Obtaining an egg from the female partner may be unsuccessful.

3. The male partner may be unable to supply a semen specimen.

4. The egg(s) may be immature or abnormal precluding fertilization. However, we have been

informed that in rare situations no fertilization may also occur even though all monitored parameters of egg and sperm function appear normal. We understand that we can request that "intracytoplasmic sperm injection" (ICSI) **must** be performed on some or all of our mature oocytes in an attempt to minimize the possibility of a no fertilization outcome and that we will be charged for this micromanipulation procedure.

We request _____ / do not request CRG-M MMG **that ICSI must be performed on our mature oocytes.**
(Please initial to indicate your decision)

5. The egg(s) may be fertilized abnormally (1 or 3 or more pronuclei).

6. Cleavage or cell division of the fertilized egg(s) may not occur.

7. The embryo(s) may be determined to be unsuitable for transfer or cryopreservation because of a slow division rate, degenerative changes or other indications of abnormal development.

8. The embryo(s) may not implant into the wall of the uterus.

9. A laboratory accident may result in loss or damage to the fertilized egg(s) or embryo(s).

10. We understand that PIVF will be responsible for the disposal and/or distribution for research purposes of fluids and tissues (including sperm, immature and non-fertilized oocytes and/or abnormally fertilized and otherwise non-viable embryos) that are routinely discarded in the course of these procedures. We understand that it is our decision to release these tissues and embryos for research purposes. Moreover, we understand that these embryos will never be used to initiate a pregnancy in another individual.

We authorize _____ / decline C.R.G - M MMG **the release of our fluids, non-germ cells and sperm and immature and non-fertilized oocytes for research purposes.**

We authorize _____ / decline C.R.G-M MMG **the release of our abnormally fertilized and / or non-viable embryos for research purposes.**
(Please initial to indicate your decisions)

C. I and my partner understand that the following are risks and discomforts associated with this procedure:

1. From the blood drawing or drug administration - mild discomfort and a risk of developing a bruise at the needle site.

2. From the "fertility drugs" - the rare development of over-stimulation of the ovaries, resulting in a condition called Hyperstimulation Syndrome. I understand that, in its most severe form, this condition requires hospitalization for intravenous fluids and monitoring until the syndrome resolves. I therefore assume responsibility for maintaining close contact with the PIVF physicians during the time I receive this medication and during the following two (2) weeks. An epidemiologic study has suggested a potential risk of developing ovarian cancer for certain groups of women following the use of these drugs, and this issue is still under investigation.

3. From the corticosteroid (Medrol) treatment a vaginal infection may develop. Other potential side effects may include a masking of infection and impaired wound healing; increases in blood pressure; alterations of salt and water retention and excretion; gastrointestinal disturbances such as nausea, vomiting diarrhea, abdominal distension and appetite loss; skin rashes, allergic reactions and hypersensitivity reactions resulting in shock; blood diseases including reduced platelets or fractured red blood cells which occur with anemia/bleeding; mood swings, vertigo insomnia, sweating, headache, psychotic manifestations and depression; and loss of muscle mass and osteoporosis. These side effects are highly unlikely because the duration of the corticosteroid treatment is so short.

4. From the ultrasound examinations - some discomfort, but there is no risk from this procedure, presently known to medical science.

5. From the ultrasonographic-guided follicular aspiration - the possibility of bleeding, infection or injury to abdominal organs that may require immediate major surgery; moderate discomfort after the procedure; and the risk associated with the sedation.

6. From the transfer of the embryo(s) into the uterus - cramping, discomfort, risk of developing infection, and possible bleeding. In addition, should an embryo(s) implant in the Fallopian tube, an ectopic pregnancy would result requiring major surgery for treatment.

7. My partner and I have been informed that transfer of more than one embryo could result in multiple gestation (twins, triplets, etc.), with an increased risk of premature labor, other maternal complications, an increased financial cost and emotional stress. Multifetal reduction (termination of one or more embryos) is an available alternative with its own attendant risks and benefits.

8. Psychological stress.

D. I and my partner understand that there is no guarantee that this procedure will result in a successful pregnancy, although the members of the PIVF team hope that a pregnancy will result from this procedure. From presently available information on IVF procedures conducted at PIVF Program (9/1/95 - 12/31/99), we understand that the chances are 43% (1312/3020) that we will achieve a clinical pregnancy following oocyte retrieval in a single IVF cycle, but that they depend on the female partner's age and may be as high as 51% (1090/2134) or as low as 25% (222/886) if she is less or greater than 40 years of age, respectively. These numbers include cases in which ICSI was performed. In some instances these chances may increase slightly following "assisted hatching." We are aware that many factors influence the outcome of IVF procedures; our questions about our individual chances for success have been answered by our physician.

If no pregnancy results from this cycle of IVF-ET, we understand that we may be offered participation in future cycle if an assessment of the treatment cycle by the PIVF team reveals no contraindications to further participation in the program.

However, should a pregnancy result from this procedure, I and my partner understand that the pregnancy may need to be monitored by weekly hormone determinations of the maternal blood and by ultrasound examination. We understand that, even if pregnancy is successfully established, the pregnancy will be subject to all the risks and complications of a natural occurring pregnancy, including without limitation, the possibility of miscarriage, ectopic or tubal pregnancy, stillbirth and/or congenital abnormalities (birth defects). The risk of the development of an abnormal fetus is at this time unknown. From animal experimentation and from observations of the abortion of abnormal fetuses in the human, although it is not known, it is now believed that the IVF-ET procedures, including ICSI and "assisted hatching" do not have any greater risk of abnormal fetal development than occurs in nature. Thus, although IVF births to date have not demonstrated an increased incidence of fetal abnormalities compared to non-IVF babies, we understand that the IVF team cannot guarantee the normalcy of any infant resulting from this procedure. A recent study has suggested a higher frequency of sex chromosome anomalies may occur following ICSI. This increase is most likely related to the use of ICSI for severe male factor infertility, which is often the result of minute deletions in the genes on the Y, or male, chromosome which would then be passed on to any male progeny. In the event that any serious abnormality is discovered, the various alternative courses of action, including elective termination of the pregnancy, will be outlined and discussed either by our PIVF physician or obstetrician as is appropriate, with the final decision on the course of action residing with us.

E. I and my partner understand that data from our IVF procedure must also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on <u>all</u> assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on us, the CDC has applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308 (d). This means that any information that the CDC has that identifies us will not be disclosed to anyone else without our consent. Thus, we understand that we cannot choose to have our information excluded and agree to provide PIVF with information regarding our pregnancy, labor and delivery, and birth outcome. We understand that it is important for us to remain in contact with PIVF; thus, we agree to advise PIVF promptly in writing of any change(s) in our mailing address or telephone number.

F. I and my partner understand that insurance coverage for any or all of the above procedures may not be available and that we will be personally responsible for the expenses of this treatment. The expenses may consist of program charges including laboratory and technical fees and professional fees, as well as medical care and, if necessary, hospitalization in the event physical injury occurs.

G. I and my partner confirm that the nature of in vitro fertilization and embryo transfer (IVF/ET) with ICSI and/or "assisted hatching" has been explained to us, together with the known risks. We understand the explanation(s) that has been given. We have had the opportunity to ask any questions we might have and those questions have been answered to our satisfaction. Any future questions we have may be addressed to the clinical staff at NYUMC or to the Program Director, Dr. Alan S. Berkeley (212-263-8990). We acknowledge that in vitro fertilization and embryo transfer are being performed at our request and with our consent with the options for ICSI and/or "assisted hatching" as indicated above. We understand that we may elect not to continue with this procedure at any time and that this decision would not affect present or future medical care and treatment.

Chaya Rachel Grossbaum-Morgenstern
Signature of Female Patient

Chaya Rachel Grossbaum-Morgenstern 3/3/04
Print Name and Date

Signature of Male Partner

[illegible] 4/19/04
Print Name and Date

Signature of Witness FOR Female/Male Partner

Kaycian Brown FOR Female/Male Partner
Print Witness Name and Date

This consent form must be signed by both the patient and her partner in the presence of a member of the clinical or nursing staffs at PIVF or in the presence of a notary public.

I have consulted with and explained the contents of this consent form to the patient and her partner. All question(s) concerning the procedures have been answered.

Signature of Physician

Print Physician Name and Date

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

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and Infertility

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CONSENT FOR CRYOPRESERVATION OF FERTILIZED EGGS / EMBRYOS

This consent form contains our directions regarding the use and disposition of fertilized eggs/embryos obtained during an IVF or an Oocyte Donation cycle at NYU School of Medicine - Program for In Vitro Fertilization, Reproductive Surgery and Infertility (PIVF).

As participants in PIVF, we, Chaya Rachel Grossbaum Mofenstern and Menachem Mendel Grossbaum, understand that more fertilized eggs/embryos may form than our physicians would recommend to be transferred during an IVF cycle or an Oocyte Donation cycle. We **consent** CRG-MM **do not consent** ____ to have these extra fertilized eggs/embryos cryopreserved (frozen and stored in liquid nitrogen) so that they can be transferred to the female partner in some later cycle for the purposes of establishing a pregnancy.

We understand that there is no guarantee that the fertilized eggs/embryos will survive the freezing process or that pregnancy can occur. We also understand that, in rare instances, mechanical failures can occur at any point in the process resulting in the loss of some or all of the fertilized eggs/embryos and we will not hold NYU School of Medicine, PIVF, or its physicians or employees responsible for any destruction, or damage resulting from such mechanical malfunctions or from those arising from fire, wind, earthquake, flood or other catastrophes.

All decisions about the disposition of the fertilized eggs/embryos are to be made jointly by both of us, except where the disposition is affected by applicable laws or decisions of courts with jurisdiction over the fertilized eggs/embryos. We can change our decisions about the disposition of the fertilized eggs/embryos by providing PIVF with written notice of the change. We understand that it is important for us to remain in contact with PIVF as long as our embryos are stored there; thus, we agree to notify PIVF promptly in writing of any change(s)in our mailing address and/or telephone number.

When we are ready to have the fertilized eggs/embryos transferred to the female partner, we will sign a Release Form to authorize the thawing of our fertilized eggs/embryos one, two or three at a time to yield an appropriate number of embryos for transfer based on the female partner's age and clinical history. Only those fertilized egg/embryos considered to be potentially viable by reasonable medical standards will be transferred into the uterus by means of a small tube inserted through the cervix. We understand after thawing it is possible that none of the fertilized eggs/embryos will be considered to be potentially viable. We have been informed that the transfer of more than one embryo could result in multiple gestation (twins, triplets or more) with an increased risk of premature labor, other maternal complications, an increased financial cost and emotional stress. Multifetal reduction (termination of one or more embryos) is an alternative option with its own attendant risks and benefits.

Transfer of the fertilized eggs/embryos to the womb requires a normal lining and a very close synchronization to the normal process of ovulation. We understand that determining this will require monitoring at PIVF which consists of daily blood tests and ultrasound examinations of the female and that the administration of gonadotropin releasing hormone agonist, estrogen and progesterone may be necessary. Fertilized eggs/embryos will only be thawed and transferred if the cycle is determined to be normal in all respects by a PIVF physician. We understand that there are risks with estrogen and progesterone administration including

an increase in blood clotting, an increased risk of gall bladder and liver disease and a possible predisposition to breast cancer; uterine cancer has been reported from estrogen intake. However, since the doses utilized resemble the normal menstrual cycle, these complications are not expected to occur

We understand that there is no guarantee that the fertilized eggs/embryos will survive the freezing or thawing procedures or that successful pregnancy will result from their transfer to the uterus of the female partner. However, should a successful pregnancy be established, we understand that the pregnancy may need to be monitored by weekly determinations of her blood and by ultrasound examination of her uterus. We understand that, even if established, this pregnancy will be subject to all the risks and complications of a naturally occurring pregnancy, including without limitation, the possibility of miscarriage, ectopic or tubal pregnancy, stillbirth and/or congenital abnormalities (birth defects). Currently, there is no information from studies on human and animal live births resulting from the transfer of cryopreserved embryos to suggest that this preservation procedure creates an increased risk of obstetrical complications or fetal anomalies.

We understand that the freezing process is intricate and time-consuming and that we are responsible for all related expenses. The freezing currently costs **$1250.00** for all fertilized eggs/embryos regardless of the number. Each time some of the fertilized eggs/embryos are thawed, the laboratory charge will be **$ 600.00** (see charges for Embryology Services for a Frozen Embryo Transfer). After twelve (12) months in storage, a quarterly storage charge of **$ 250.00** will be imposed. Such expenses are subject to change. We understand and agree that PIVF is entitled to and will view these fertilized eggs/embryos as "abandoned" if we fail to pay these storage charges on a timely basis, i.e. within 60 days after receipt of a quarterly notice. With respect to such abandoned fertilized eggs/embryos, we agree that PIVF shall have the right to dispose of them if we have not paid storage charges, provided that PIVF has notified us by certified or registered mail (receipt requested) to our address as it appears on PIVF records at least 60 days prior to disposing of the abandoned fertilized eggs/embryos.

We understand that data from our frozen embryo transfer procedure must also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on us, the CDC has applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308 (d). This means that any information that the CDC has that identifies us will not be disclosed to anyone else without our consent. Thus, we understand that we cannot choose not to have our information included and agree to provide PIVF with information regarding any future pregnancy, labor and delivery, and birth outcome resulting from the transfer of these cryopreserved embryos. We understand that it is important for us to remain in contact with PIVF; thus, we agree to advise PIVF promptly in writing of any change(s) in our mailing address or telephone number.

We understand that while the fertilized eggs/embryos are frozen, certain new circumstances may arise. Some are described below; check all options that apply:

1. In the event of death of the male partner, we wish the fertilized eggs/embryos to be:

   a. ___ transferred to the female partner
   b. ___ donated for research purposes
   c. X thawed and no further action taken
   d. ___ other (explain) _____

2. In the event of the death of the female partner, we wish the fertilized eggs/embryos to be:

   a. ___ transferred at the discretion of the male partner
   b. ___ donated for research purposes
   c. X thawed and no further action taken
   d. ___ other (explain) _____

3. In the event of both of our deaths or if the surviving partner does not wish to accept them, we wish the fertilized eggs/embryos to be:

   a. ___ donated for research purposes
   b. X thawed and no further action taken
   c. ___ other (explain) _____

4. In the event of our divorce, we wish the fertilized eggs/embryos to be:

   a. ___ made available to female partner _____
   b. ___ made available to male partner _____
   c. ___ donated for research purposes
   d. X thawed and no further action taken
   e. ___ other (explain) _____
   f. ___ we do not wish to make this decision now

5. Should we decide, after a period of time, to "abandon" our fertilized eggs/embryos by request or by failure to pay PIVF storage charges, we wish the fertilized eggs/embryos to be:

   a. ___ donated for research purposes
   b. X thawed and no further action taken
   c. ___ other (explain) _____

Cheryl Rachel Grossbaum-Meyerstein 3/31/04 — 4/19/04

Signature of Female Partner — Date — Signature of Male Partner — Date

3/31/04 — 4/19/04

Signature of Witness — Date — Signature of Witness — Date

This consent form must be signed by both partners in the presence of a member of the clinical, nursing or embryology laboratory staff at PIVF or in the presence of a notary public.

I have consulted with and explained the contents of this consent form to the patient and her partner. All questions concerning the procedures have been answered.

Physician _____ Date _____

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Addendum to IVF/ET Transfer Consent – Embryo Biopsy and Preimplantation Genetic Diagnosis (PGD)

I Chaya R. Grossbaum-Morgenstern and my partner Menachem M. Grossbaum are known to be carriers for a genetic disorder:

____ X Chromosome-linked disorder ____ Recurrent aneuploidy ____ Chromosome translocation

✓ Single gene disorder Cystic Fibrosis

(e.g. Marfan's syndrome, Cystic fibrosis, Tay-Sachs, Fanconi's anemia, Von Hipple Landau syndrome, Epidermolysis bullosa)
(Please initial the specific genetic disorder that you carry.)

Because we do not wish to have any future children affected with a genetic disorder, we request that the embryos generated during our In Vitro Fertilization (IVF) cycle be biopsied and analyzed for the genetic disorder cited above. We understand that this procedure, preimplantation genetic diagnosis (PGD), can detect numerous genetic disorders in the embryo before it is transferred to the uterus and, when successful, allows for the possibility of pre-selecting "normal" embryos for conception, thus reducing the chance of giving birth to a child afflicted with a hereditary disease. We have been referred for PGD to the Program for In Vitro Fertilization, Reproductive Surgery and Infertility (PIVF) at the NYU School of Medicine where the IVF and biopsy procedures will be performed under the supervision of Dr. James A. Grifo M.D., Ph.D.. Genetic diagnosis of the cells, or blastomeres, removed from the embryos will be performed either at St. Barnabas Medical Center, West Orange, NJ or at the Center for Molecular Medicine and Genetics at Wayne State University, Detroit, MI.

We understand that the following steps are required:

1. Whenever appropriate, blood from each of us (approximately 10 milliliters) will be tested to verify that the diagnostic methods can detect the particular genetic disorder that we carry. This is particularly important whenever our samples are to be sent to the Center for Molecular Medicine and Genetics for analysis.

2. We will undergo an IVF treatment cycle at the Program for In Vitro Fertilization, Reproductive Surgery and Infertility in order to generate embryos for biopsy and analysis. We have signed the "In Vitro fertilization / Embryo Transfer ('IVF-ET') Program Consent Form – Options for 'Intracellular Sperm Injection' and 'Assisted Hatching' "of the Program for IVF (PIVF) which details the procedures and risks associated with the IVF procedure. We understand that we might require intracellular sperm injection (ICSI), the microsurgical injection of a single sperm using micromanipulators under an inverted microscope to fertilize the eggs, and have agreed to this option and have read the risks associated with ICSI as stated in the IVF consent form.

3. On day 3 post egg retrieval each embryo containing 5 or more cells (blastomeres) will be subjected to a microsurgical biopsy in order to remove one or two cells. This procedure is also carried out using micromanipulators under a microscope . Should the female partner carry a chromosomal translocation a similar procedure will also be used to remove the first polar body of each egg prior to insemination. The biopsy procedure involves drilling a small hole through the zona pellucida of the embryo, a procedure which also "assists" with the hatching of the embryo as a blastocyst at a later stage of development. The cell(s) are gently removed from the embryo by suction. .

4. Genetic analysis of each polar body and/or blastomere will then be performed to determine its sex or if it carries our specific genetic disorder. Depending on our genetic disorder, we understand that the biopsied blastomeres will be analyzed using either fluoresence in situ hybridization (FISH, a procedure that enables us to count the numbers of certain chromosomes to check for sex, aneuploidy or translocations) or by molecular biology procedures designed to detect specific gene mutations. When FISH procedures are to be used, the blastomeres will be analyzed at St. Barnabas Medical Center, West Orange, NJ. When molecular biology procedures are to be used, the blastomeres will be analyzed at the Center for Molecular Medicine and Genetics at Wayne State University, Detroit, Michigan. We understand that will also be required to sign the appropriate consent form for these institutions. Genetic results will be available within 2 days following biopsy.

5. After the microsurgery, the embryos will be grown for one or two days after which time the "normal" embryos, i.e., those embryos with highly reduced possibilities of developing our specific genetic disorder – either unaffected embryos or, in cases where two mutations must be present to for the genetic disorder to appear, "carrier" embryos which carry only one mutation, will be transferred to uterus of the female partner should we decide in favor of such a transfer. We understand that it is possible that there may be no "normal" embryo available for transfer.

6. If there are "normal" embryos of suitable quality for future attempts to initiate a pregnancy using a frozen embryo transfer, these embryos may be cryopreserved with our permission. Details about cryopreservation are presented in the PIVF "Consent for cryopreservation of fertilized eggs/embryos" that we must also sign. ***Affected embryos carrying the genetic disorder or "normal" embryos displaying such poor development and morphology to be highly unlikely to initiate a pregnancy will be retested whenever possible and then discarded.***

7. Following embryo transfer, blood tests for human chorionic gonadotropin, a sign of pregnancy,will be conducted and once established, our pregnancy will be followed in a routine fashion. Fetal development will be carefully monitored by serial ultrasound studies. In addition, in order to confirm the genetic diagnosis, we agree that the female partner will undergo chorionic villus sampling or amniocentesis at the appropriate time, 10 weeks and 12-16 weeks respectively, and to inform PIVF of the outcome.

8. Finally, we understand that it is important for us to monitor the growth and development of our child(ren) carefully during the first 2 years of life with our pediatrician at his/her discretion.

We understand that the following risks may be associated with the PGD procedure :

1. We have been informed that the IVF procedure has a number of defined risks that happen very infrequently (less than 1%). These risks are detailed in the In Vitro Fertilization/Embryo Transfer ("IVF-ET") Program Consent Form -Options for "Intracellular Sperm Injection" and "Assisted Hatching" that you must also sign and include infection, bleeding, ovarian hyperstimulation syndrome, premature birth, ectopic pregnancy, miscarriage and failure to conceive. The risks associated with multiple pregnancies are also listed in the Program Consent Form for IVF.Multiple pregnancy, i.e., twin and triplet pregnancies, carry a significantly greater risk for prematurity and obstetrical and neonatal anomalies and occur at a

Initial: GRM-G MMG
Date: 6/04/04